

**REMARKS**

Applicant submits that the present amendment is fully responsive to the Office Action dated September 22, 2009 and, thus, the application is in condition for allowance.

By this reply, claims 50, 53, 59 and 62 are amended. Claims 68-75 are newly added, are fully supported by the application as filed, and introduce no new matter. Claims 50, 53, 56, 57, 59-62 and 65-75 remain pending. Of the pending claims, claims 50, 53, 59 and 62 are independent. An expedited review and allowance of the application is respectfully requested.

At the onset, Applicant's representative extends his sincere gratitude to Examiner of record Ou and Primary Examiner Julian Woo for graciously agreeing to an interview at the USPTO on February 22, 2010. During such interview, Applicant's representative presented a description of the invention, particularly pointing out some of the many advantages of the exemplary embodiments of the present invention. Then the cited art of record was discussed, and how the present invention is distinguishable over the cited art of record. For example, none of the cited art of record, alone or in combination, disclose or fairly suggest a device which includes suture passing member with a puncturing projection which is slidable along the lumen of a body and extends beyond one of the jaws having a transverse opening therein. None of the art of record teaches a device having suture which is substantially outside of the outer tubular member of the body. Applicant's unique geometry and design have advantages that were not appreciated or inherent in the device of the references cited, which either show a straight needle configuration and associated device, or a curved needle and associated device, or devices which push suture completely through the device. These references are not combinable in any manner as the straight needle device simply cannot operate with a curved needle and the curved needle device simply cannot operate with a straight needle. The present amendment reflects the clear

distinctions between the art of record and the present invention. An allowance of the claims is respectfully requested.

In the outstanding Office Action, claims 50, 53, 56, 57, 59-62 and 65-67 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Haber (U.S. Pat No. 5,342,389) in view of Sachdeva (U.S. Pat. No. 5,607,435) in view of Caspari (U.S. Pat No. 4,923,461). It is asserted that Haber discloses substantially the same invention as recited in the pending claims but for “the distal portion of the elongate member having superelastic properties and one of the jaws having an opening; wherein the distal portion of the elongated member is in a stressed configuration substantially contained within the lumen of the cylindrical body in a first position and in an unstressed configuration in a second position.” It is further asserted that Sachdeva and Caspari do teach these deficiencies and thus it is concluded that the combination of these three references would render the present claims as obvious. Applicant respectfully traverses.

Neither Haber, nor Sachdeva, nor Caspari, nor any other reference of record, alone or in combination, can teach or fairly suggest the present invention as recited in the pending claims. In general, none of the references of record teach a superelastic puncturing projection that extends through one of a pair of jaws. The references either show a rigid, static needle that goes from one jaw to another (Caspari) or passes straight between and along the jaw line (Haber) or show no jaws at all (Sachdeva). The references, and in particular, Haber, does not teach or suggest, among other things, a superelastic needle which is in a first resting stressed configuration while inside of a tubular member, and a second relaxed position as it slides through and beyond a transverse opening in one of the jaws. Haber shows parallel jaws 10, 12 (to crimp the tissue into multiple folds) with a needle 88 that passes straight along the same axis as the hollow tube and needle, and never through a transverse hole in either jaw. The needle 88

punctures the tissue in/out multiple times, thereby creating a classic purse-string suture. This straight needle approach is completely different from the present invention as recited in the pending claims.

Furthermore, Sachdeva cannot cure the deficiencies of Haber because Sachdeva does not teach or suggest, among other things, a tubular structure having jaws, one having a transverse opening through which a superelastic needle passes as the jaws grip the tissue. Such teaching is completely lost on Sachdeva. Instead, Sachdeva uses a tube 72 in place of a needle, as recited in the pending claims. The suture is threaded through the interior of the tube 72 once the tube is passed through the tissue. See, for example, Figs. 4 and 6. There is no concept of a superelastic needle carrying suture. Furthermore, there are no jaws or the concept of a jaw through which a superelastic needle carries suture through tissue through a transverse opening in one of the jaws.

Finally, Caspari also fails to cure the deficiencies of Haber because Caspari also fails to teach, among other things, a superelastic needle which is in a first resting stressed configuration while inside of a tubular member, and a second engaged relaxed position as it slides through and beyond a transverse opening in one of the jaws. Caspari teaches a hollow, static needle 56 that pierces tissue as the jaws 34, 44 are clamped. The suture 122 is threaded through the tube inside the needle 56 using roller wheels. The needle 56 does not carry the suture, particularly in a transverse opening, as recited in the pending claims. Furthermore, the needle 56 is fixed to and part of the jaw 34, and never changes shape. In fact, if the needle 56 changed shape, the Caspari device simply would not work.

Thus, although each reference is being used to allegedly disclose some element(s) of the present invention as recited in the pending claims, each reference has glaring functional and feature deficiencies. There is no motivation to combine these three very different references.

Even if there was some motivation to combine them, *arguendo*, the combination would not be able to render the present claims as obvious because the combination would simply not work. It is inconceivable how Haber, which absolutely relies on the criticality of a straight needle, would work with a superelastic (Sachdeva) or curved (Caspari) needle. The grooves in the jaws (see Haber, Fig. 1) are especially designed to house and guide a straight needle therethrough. They are specifically designed to be straight and cannot in any way be conceived to be anything other than straight. Thus, any use or intention of a curved path would destroy the very function of Haber. Thus, Haber is simply not combinable with any other reference that teaches a curved needle or path, such as Sachdeva and Caspari. Sachdeva does not teach, among other things, the use of jaws. As shown in Fig. 4 of Sachdeva, it is inconceivable how any jaws would be used in the Sachdeva device because such jaws, even if they would be added, would be wholly inoperable or nonfunctional as the end 48 of the hollow tube, which is where the jaws would be allegedly located, is completely outside or facing away from any intended tissue. Finally, Caspari simply cannot function with any other needle except the specific permanently curved, hollow needle 56 that it uses. It simply cannot function with a straight or superelastic needle because the needle must be curved and rigid in order for the Caspari device to operate. Thus, each of the references, besides not disclosing the features and elements recited in the pending claims, teaches a mechanism that is specific to that device and any change or alteration or combination with any of the other references would render the reference as wholly inoperable. For at least these reasons, the references cannot be combined in a functional matter to render the present claims as obvious. The rejection should be withdrawn and the claims allowed to issue.

Finally, none of the references teaches a device which carries suture completely outside of lumen of the outer hollow member. Each of the art of record teaches a device in which the

suture must be pushed through the outer hollow member of the device. In fact, Caspari and Sachdeva even teach hollow needles through which the suture must be pushed through. Finally, none of the references of record teach a flexible, closed-loop eyelet in the suture carrying needle. Thus, for at least all of these distinctions, all pending claims should be allowed and the application allowed to proceed to issue.

A THREE (3) month extension of time is hereby requested to enter this amendment. If any other fees are associated with the entering and consideration of this request for consideration, please charge such fees to our Deposit Account 50-2882.

As all of the outstanding rejections have been traversed and all of the claims are believed to be in condition for allowance, Applicant respectfully requests issuance of a Notice of Allowance. If the undersigned attorney can assist in any matters regarding examination of this application, Examiner is encouraged to call at the number listed below.

Respectfully submitted,

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/Fariborz Moazzam, Reg. No. 53,339/

Fariborz Moazzam

Reg. No. 53,339

Cust. No. 39,013

MOAZZAM & ASSOCIATES, LLC  
7601 Lewinsville Road, Suite 304  
McLean, Virginia 22102  
(703) 442-9480 (office)  
(703) 991-5978 (fax)